K062221

510(k) Summary

Prepared: February 2006

AUG 17 2006

Submitter:

Company Name: Canon USA, Inc. (U.S. agent for Canon Inc.)
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Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40EC
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-40EG/CXDI-40C
Classification Name:	90MQB, Solid State X-ray Imager
FDA 510(k) #:	K050987/ K031633

Description Of Device: The Canon digital radiography CXDI-40EC is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a DICOM compatible digital network for printing. The device provides digital image capture for conventional film/screen radiographic examinations.

The Canon digital radiography CXDI-40EC is different from CXDI-40EG and CXDI-40C in the following respect:

- Both the CXDI-40EC and the CXDI-40EG use the same amorphous silicon alley as the sensing means, however, the CXDI-40EC uses the different material for fluorescent screen which is deposited on the amorphous silicon array with from the CXDI-40EG. The CXDI-40EC uses CsI (Cesium Iodide) while CXDI-40G uses GOS (Gadolium Oxy-Sulfide). Because of CsI which provides high x-ray absorption as fluorescent screen, CXDI-40EC delivers diagnostic images with approximately half the x-ray dosage required by CXDI-40EG and CXDI-40EC's DQE approximately doubles compared to CXDI-40EG.

The principle of the CXDI-40EC is the same as the CXDI-40C. The sensor of the CXDI-40EC has the same characteristics as the CXDI-40C. The CXDI-40EC itself is a component without a control PC. Using a general-purpose computer with appropriate specifications and the designated system software installed in it, as a control PC, the CXDI-40EG

achieves performance stated herein(such as image capturing, DICOM transfer and etc.)

Intended Use:

Canon digital radiography CXDI-40EC provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. This device is not intended for mammography applications.

Descriptive Comparison

The predicate devices are the Canon digital radiography CXDI-40EG cleared under Document Number K050987 on April 27, 2005 and CXDI-40C cleared under Document Number K031633 on June 11, 2003.

The CXDI-40EC's amorphous silicon array specifications (including image size, pixel pitch, number of pixels), imaging principle and intended use are the same as those of CXDI-40EG and of CXDI-40C. However, the differences in the design are as follows:

- Both the CXDI-40EC and the CXDI-40EG use the same amorphous silicon array as sensing means, however, the CXDI-40EC uses the different material for fluorescent screen which is deposited on the amorphous silicon array with from the CXDI-40EG. The CXDI-40EC uses CsI (Cesium Iodide) while CXDI-40EG uses GOS (Gadolium Oxy-Sulfide).
- Because of CsI which provides high x-ray absorption as fluorescent screen, CXDI-40EC delivers diagnostic images with the x-ray dosage less than that required by CXDI-40EG and CXDI-40EC's DQE approximately doubles compared to CXDI-40EG.
- The CsI used in CXDI-40EC as fluorescent screen is equivalent to the material used in the other devices of the same intended use in the market.
- Both the CXDI-40EC and the CXDI-40C use the same amorphous silicon array as sensing means and also uses the same material for fluorescent screen of CsI (Cesium Iodide) but are controlled with a different interface of PC.
- A removable, fixed grid is used for all of the CXDI-40EC, CXDI-40EG and the CXDI-40C. Those grids are instated inside the sensor housing and used for eliminating the scatter X-ray in exposures that use films.

(See attached Table 4.2)

Regarding the software:

- The system software for controlling CXDI-40EC is released as V6.3.
- V6.3 includes some changes from V6.0.
- The main changes of the V6.3 are the addition of the control of CXDI-40EC sensor and some change of GUI.
- V6.0 was first introduced and cleared under K031447 and is currently used in Canon models the CXDI-50G.

Based on the information in this submission, similarity to the predicate devices (the Canon digital radiography CXDI-40EG and the CXDI-40C), and the results of our design control activities, it is our opinion that the Canon digital radiography CXDI-40EC described in this submission is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Document Control Room – WO66-G609
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Canon USA, Inc.
% Mr. Jeffrey D. Rongero
Senior Project Manager
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
MELVILLE NY 11747

AUG 23 2013

Re: K062221
Trade/Device Name: CDXI-40EC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 27, 2006
Received: August 2, 2006

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of August 17, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 3: Statement

Indications for Use

510(k) Number (if known): K062221

Device Name: CXDI-40EC

Indications for Use:

DIGITAL RADIOGRAPHY CXDI-40EC provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062221